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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/748,896  | 12/30/2003  | Scott A. Tufts       | MDFX.102621         | 7423             |
| 5251  | 7590        | 04/05/2005           | EXAMINER            |                  |
| SHOOK, HARDY & BACON LLP<br>2555 GRAND BLVD<br>KANSAS CITY,, MO 64108 |             |                      | WALCZAK, DAVID J    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |

3751

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/748,896 | Applicant(s)<br>TUFTS ET AL. |  |
|                              | Examiner<br>David J. Walczak  | Art Unit<br>3751             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-21 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/2/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Abstract***

The abstract of the disclosure is objected to because phrases which can be implied, such as "The/the present invention relates" (see lines 1 and 2) should not be present therein. Correction is required. See MPEP § 608.01(b).

### ***Specification***

The disclosure is objected to because of the following informalities: In paragraph 0043, line 9, "crush portion 38" should be --crush portion 36--. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In regard to claim 21, the step of "coupling" a lever to the body after providing a body and preceding securing a porous element to the body does not have antecedent basis in the specification.

### ***Claim Rejections - 35 USC § 112***

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. An antecedent basis for "the porous plug" should be defined.

It appears that claim 17 should depend from claim 16, as opposed to claim 1 as the porous plug is first defined in claim 16.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tufts in view of Kaufman. In regard to claims 1 and 18, Tufts discloses a liquid applicator for pre-surgical scrubbing comprised of a frangible ampoule 14, an elongated hollow body 12, a lever mechanism 28 that flexes the body inwardly to fracture the ampoule and a porous element 16. Although the Tufts reference does not disclose the use of two ampoules, attention is directed to the Kaufman reference, which discloses another applicator for pre-surgical scrubbing (see the abstract) wherein two frangible ampoules 142 are disposed therein and simultaneously fractures (see column 12, lines 16-19) in order to enable a user to simultaneously dispense two fluids. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include two frangible ampoules in the Tufts device (which would be simultaneously fractured by the lever) in order to enable a user to dispense plural materials. In regard to claim 2, the lever includes a hinge portion (wherein lever 28 mates with the body, see Figure 5), a crush portion 38 and a handling portion 32. In

regard to claim 3, the body has a central longitudinal axis. In regard to claim 4, the lever extends at an angle of between 20 and 40 degrees with respect to the axis (column 5, lines 27-30). In regard to claim 5, the crush portion flexes the body inwardly to fracture the ampoule. In regard to claim 6, the portion of the body that is flexed inwardly is considered to be a "thin wall portion". In regard to claim 7, the lever is curved. In regard to claim 8, the lever includes a "support rib" between the crush portion and the handling portion. In regard to claim 9, viewing Figure 5, the hinge portion (the part of the lever which melds into the body) is thinner than the rest of the lever. In regard to claim 10, the gripping area of the handling portion is larger than the area of the crush portion of the lever. In regard to claim 11, the handling portion is textured at 34. In regard to claim 12, the body has opposite closed and open ends. In regard to claims 16 and 19, a "porous plug" 17 exists between the porous element and the ampoule(s). In regard to claims 17 and 20, a "restraint element" 24 is positioned between the ampoule(s) and the porous plug. In regard to claim 21, the method as claimed is inherent in the assembling of the Tufts device.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tufts in view of Kaufman, as applied to claim 12 above, and further in view of Hoang et al. (hereinafter Hoang). Although the Tufts device does not include a cap for covering the closed end or a vent therein, attention is directed to the Hoang reference, which discloses another device for applying a pre-surgical scrub wherein the body is closed at the end thereof by a cap 21 which includes a vent therein (see column 4, lines 4-8) in order to enable the body to be vented and in order to enable a user to have

access to the interior of the body. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include such a cap and vent onto the Tufts device in order to enable the user to have access to the body and in order to enable the body to be vented.

### ***Allowable Subject Matter***

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Krawczyk et al., Frazier and Jarrett references are cited for disclosing other containers having frangible ampoules therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Walczak whose telephone number is 571-272-4895. The examiner can normally be reached on Mon-Thurs, 6:30- 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Walczak  
Primary Examiner  
Art Unit 3751

DJW  
3/31/05